

(19) World Intellectual Property
Organization
International Bureau



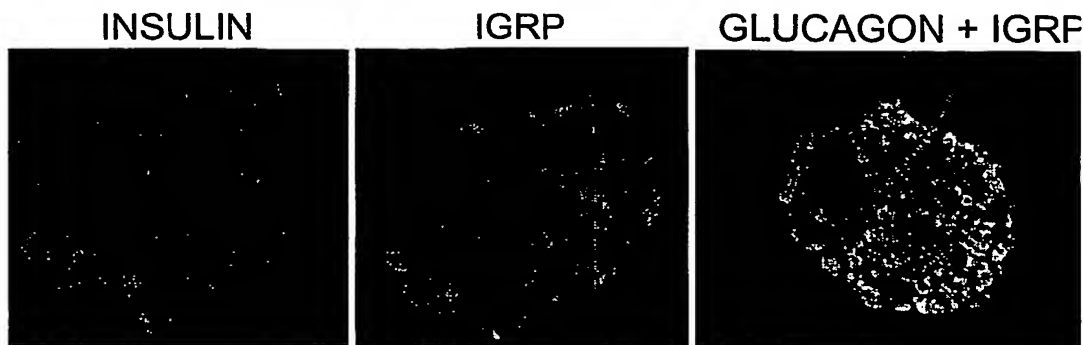
(43) International Publication Date
7 April 2005 (07.04.2005)

PCT

(10) International Publication Number
WO 2005/030032 A2

- (51) International Patent Classification⁷: **A61B**
- (21) International Application Number:
PCT/US2004/030772
- (22) International Filing Date:
20 September 2004 (20.09.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/505,317 22 September 2003 (22.09.2003) US
- (71) Applicant (for all designated States except US): **THE REGENTS OF THE UNIVERSITY OF COLORADO** [US/US]; 201 Regent Administrative Center, 3 SYS, Boulder, CO 80309 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **HUTTON, John, C.** [US/US]; 1324 Birch Street, Denver, CO 80220 (US). **O'BRIEN, Richard** [US/US]; 729 Jones Parkway, Brentwood, TN 37027 (US). **DAVIDSON, Howard** [GB/US]; 3333 E. Bayaud Avenue Apt.504, Denver, CO 80209 (US). **HACKL, Seija** [FI/US]; 4274 Halifax Way, Aurora, CO 80013 (US).
- (74) Agents: **TRAVER, Robert, D.** et al.; Sheridan Ross P.C., 1560 Broadway, Suite 1200, Denver, CO 80202-5141 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— without international search report and to be republished upon receipt of that report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: USE OF ISLET GLUCOSE-6-PHOSPHATASE RELATED PROTEIN AS A DIAGNOSTIC TOOL AND THERAPEUTIC TARGET FOR AUTOIMMUNE DIABETES



(57) Abstract: A method and compositions for detecting autoimmunity to islet glucose-6 phosphatase related protein (IGRP). Detection of IGRP autoantibodies alone, and in combination with other molecules such as the 65-kDa form of glutamate decarboxylase (GAD₆₅), insulin and insulin granule membrane proteins ICA512 (IA-2) and phogrin (IA2 β) auto-antigens, provides an effective and reliable chemical assay for the diagnosis of autoimmune (type 1) diabetes. Additionally, this invention provides therapeutic regimens based on IGRP and related molecules for the amelioration of the diabetic clinical condition. Therefore, IGRP alone or in combination with other autoimmune diabetes associated antigens such as insulin, IA-2 and GAD₆₅, is useful in the prediction (diagnosis), treatment (therapy), and prevention (prophylaxis) of diabetes.